Patent
Case No.: 54839US002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor:	AVERILL, RICHARD F.		
Application No.:	09/302336	Group Art Unit:	2166
Filed:	April 29, 1999	Examiner:	S. Rimell
Title:	METHOD OF GROUPING AND ANALYZING CLINICAL RISKS, AND SYSTEM THEREFOR		

BRIEF ON APPEAL

Board of Patent Appeals
and Interferences
Commissioner for Patents
Washington, DC 20231

CERTIFICATE OF MAILING
I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: Commissioner for Patents, Washington, DC 20231 on:
23 August 2002 Carolyn V. Peters
Date Signed by: Carolyn V. Peters

Dear Sir:

This is an appeal from the Office Action mailed on April 8, 2002. This Brief is being filed in triplicate. The fee required under 37 CFR § 1.17(c) for the appeal should be charged to Deposit Account No. 13-3723.

REAL PARTY IN INTEREST

The real party in interest is 3M Company (formerly known as Minnesota Mining and Manufacturing Company) of St. Paul, Minnesota and its affiliate 3M Innovative Properties Company of St. Paul, Minnesota.

RELATED APPEALS AND INTERFERENCES

Appellants are unaware of any related appeals or interferences.

STATUS OF CLAIMS

Claims 9 and 11 are allowed. Claims 1-8, 10 and 12 are finally rejected.

STATUS OF AMENDMENTS

No amendments have been filed after the final rejection.

SUMMARY OF THE INVENTION

The present invention creates a comprehensive set of risk groups which in particular explicitly identifies groups of individuals with multiple interacting co-morbid conditions, and which explicitly identifies the severity of illness level. This allows accurate prediction of future health care resource needs of an entire population, while simultaneously helping the health care provider isolate problems to identify changes in care to reduce costs and improve quality.

The present invention starts this process by developing a classification system that rates both the nature and severity of health care requirements, then applies that system to historical information for both individual patients and populations to group them according clinical risks. Each individual will fall into a single, mutually exclusive risk group in the classification system. Each risk group relates the historical clinical and demographic characteristics of the individual to the amount and type of health care resources that individual likely will consume in the future. Since the clinical risk groups are clinically based, they create a system that links the clinical and financial aspects of care. Thus, the clinical risk groups are designed to serve as the foundation of management systems which support care pathways, product line management and case management.

The present invention assumes there is at least one set of medical care codes available which is used to describe patient treatment. According to the present invention, the classification system is created by categorizing the medical care codes into major disease categories, and subdividing each major disease category into a plurality of episode disease categories based on the severity and/or longevity of the disease. The episode disease categories within each major disease category are ranked in seriousness, with, e.g., chronic diseases (e.g., emphysema) rated more severely than acute diseases which by their nature usually will last only a short while (e.g., pneumonia). In addition, severity of illness levels preferably are defined for episode disease categories.

In the typical situation, there in fact will be multiple sets of medical care codes, e.g., one used by hospitals and one used by physicians. Each of them can be categorized into its own sets of categories, though the level of detail applied may vary by set. For example, hospitals tend to have a far larger number of codes than physicians, so a more detailed categorization would be appropriate.

The classification system is applied to a set of historical data for an individual patient by first identifying all episode disease categories experienced by that individual. The episode disease categories within each major disease category are then adjusted to take into account to take into account the nature and timing of treatment events. For example, an individual with a history of angina, who then has angioplasty, can be expected to not have angina in the future. The episode disease category for angina therefore should be deleted, unless the angina has recurred some significant period of time (e.g., 90 days) after the angioplasty. Note that the information from multiple sets of codes may interact in this adjustment (e.g., angina often will be identified from physician records, while angioplasty will normally be identified from hospital records). The severity of illness is adjusted in a similar manner.

Once the episode disease categories have been defined and severity of illness adjusted, the primary chronic disease is identified for each major disease category. The severity of illness for each major disease category typically will be the same as that for the primary chronic disease, but may need to be adjusted if there are episode disease categories in other major disease categories which interact with it, e.g., amputation of extremities implies that a patient with diabetes is in an extremely advanced state of diabetes, which may be even worse if the patient also has congestive heart failure.

The major disease categories and their respective severity of illnesses then are aggregated in a similar fashion to identify a single clinical risk group for the individual, and an overall severity of illness for the individual.

The classification system then also defines a method for aggregating information about groups of patients, to allow the summation of information about large numbers of patients. Preferably, this involves grouping the clinical risk groups into aggregated clinical risk groups at a variety of levels.

A significant advantage to the present invention is that it allows health care providers to identify and pro-actively treat health problems. Unlike present capitation rate calculation systems, the clinical risk groups developed and used according to the present invention directly communicate information in a form and at a level of details that can lead to specific positive actions. To illustrate the difference, suppose that for individuals with diabetes the capitated payments are 25% lower than the provider's expenditures. While this is obviously useful information for identifying a problem, it does not give the provider any real information on the

precise source of the problem, or the actions that can be taken to correct the problem. In contrast, suppose the payment system also provided the following information:

"The higher costs for diabetic individuals are due to unusually high expenditures for inpatient care combined with uncommonly low expenditures for pharmacy and outpatient laboratory services for severity of illness level 1 and 2 diabetic individuals. Further a higher than expected percentage of severity of illness level 1 and 2 diabetic individuals over time become severity level 3 or 4."

Clearly, the above information raises specific questions concerning the monitoring and preventive care being provided to individuals with low severity diabetes, which gives providers a basis for management action, and an effective response to the incentives in the payment system.

Another significant advantage of the present invention is that it allows much more accurate estimations of future health care needs and costs. Given a large sample size, it is quite straightforward to determine the typical future costs for each individual in a particular clinical risk group. Those costs then can be used to weight the total cost of a group, based on the number of individuals in each clinical risk group. Similarly, the clinical risk group information can also be used to develop much more accurate predictions of future capital equipment needs, personnel needs and the like.

ISSUES ON APPEAL

Whether or not the rejected claims are anticipated by the DXCG Document.

GROUPING OF CLAIMS

The appealed claims will stand or fall together. No admission, however, is being made with respect to the obviousness of the subject matter of the dependent claims with respect to the subject matter of the independent claims. Furthermore, Appellants do not dispute the Examiner's allowance of claims 9 and 11.

ARGUMENTS OF APPELLANTS

The Examiner has maintained the reference entitled DXCG Document is four pages of screenshots obtained from DXCG.com. This document includes two sections. The first section is entitled "From Diagnosis Codes to Diagnostic Cost Groups" and "How DXCG Models Predict Resource Use."

The Examiner goes on to further described what is disclosed at the DXCG.com website.

Appellants respectfully submit that there is a fundamental distinction between the Hierarchical Coexisting Conditions (HCC) disclosed at DXCG.com and the claims of the present invention.

The severity categorization used by HCCs refers to the relationship between different diseases within a common body system rather than distinctions made within a specific disease, as is claimed in the present invention. The Clinical Risk Groups (CRGs) severity adjustment of the present invention refers to the severity of illness leveling matrix that has no HCC counterpart. For example, while HCC may identify congestive heart failure, CRGs would identify congestive heart failure and in addition, specify its relative severity, a task that is not disclosed in the documents from DXCG.com.

The Examiner has stated that the DXCG systems provides the matrix claimed by the present invention.

Appellants respectfully state Hierarchical Coexisting conditions (HCC) determine the weight given each disease group using a linear regression model which assigns a weight for each of a set of diagnostic categories. Then, where and when applicable, the weights for each diagnostic category in an individual's history are added to get a total weight. The total weight is converted into a predicted cost for the next year. For example, consider the case of individuals with diabetes and hypertension, which generally are considered independent but interactive disease processes. While diabetes does not cause hypertension, or vice versa, it is not unusual for an individual to have both. However, the additional or marginal cost for treating a diabetic with hypertension may actually be considerably less than simply adding the cost for treating a non-hypertensive diabetic to the cost for treating a non-diabetic hypertensive. This makes intuitive sense when one considers that the diabetic already is making regular office visits for the diabetes, blood pressure is routinely checked during any medical office visit, so the costs are likely not equal to the costs of treating diabetes and hypertension independently.

In contrast, the present invention creates a comprehensive set of risk groups which in particular explicitly identifies *groups of individuals with multiple interacting co-morbid conditions, and which explicitly identifies the severity of illness level* (emphasis added). This allows accurate prediction of future health care resource needs of an entire population, while simultaneously helping the health care provider isolate problems to identify changes in care to reduce costs and improve quality.

The present invention begins by developing a classification system that rates both the nature and severity of health care requirements, *then applies that system to historical information for both individual patients and populations to group them according clinical risks. Each individual will fall into a single, mutually exclusive risk group in the classification system.* Each risk group relates the historical clinical and demographic characteristics of the individual to the amount and type of health care resources that individual likely will consume in the future. Since the clinical risk groups are clinically based, they create a system that links the clinical and financial aspects of care. Thus, the clinical risk groups are designed to serve as the foundation of management systems that support care pathways, product line management and case management.

Appellants believe that the addition approach as exemplified in the DXCG.com document may not accurately represent the relationship between ostensibly independent problems, thus leading to erroneous evaluations and risk assessment valuations.

Therefore, in view of the non-disclosure of the present invention in the reference cited by the Examiner, Appellants respectfully request the Examiner withdraw all 35 U.S.C. § 102(b) rejections from the claims.

CONCLUSION

For the foregoing reasons, appellants respectfully submit that the Examiner has erred in rejecting this application under 35 USC § 102(b). Please reverse the Examiner on all counts.

Respectfully submitted,

23 August 2002
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APPENDIX

1. A method of creating a classification system for rating the nature and severity of health care requirements, characterized by:

(a) obtaining a set of medical care codes;

(b) categorizing the medical care codes into major disease categories;

(c) categorizing the medical care codes into episode disease categories based on the severity and persistence of the disease, and assigning each episode disease category to a major disease category; and

(d) sub-dividing at least some of the episode disease categories by severity of illness, wherein the classification system is applied to historical information for individuals and populations to group them according to the classification system.

2. The method of claim 1, further comprising defining a set of severity of illness levels for each episode disease category.

3. The method of claim 1, wherein at least some of the episode disease categories represent chronic conditions, and only the chronic episode disease categories are sub-divided by severity of illness.

4. The method of claim 1, further comprising defining a severity of illness leveling matrix for adjusting the severity of illness level for each episode disease category based on the nature and timing of treatment for each episode disease category.

5. The method of claim 3, further comprising:

providing a second set of medical care codes;

categorizing the medical care codes in the second set into episode procedure categories;

wherein the severity of illness leveling matrix takes account of the episode procedure categories in adjusting the severity of illness level for each episode disease category.

6. The method of claim 5, further comprising the step of creating episode disease categories which are indicated by episode procedure categories.

7. The method of claim1, further comprising defining criteria for aggregating the episode disease categories and severity of illness levels to assign an overall clinical risk group and severity of illness rating to an individual patient.

8. The method of claim 7, further comprising defining a set of selection criteria for selecting a primary chronic disease from the episode disease categories for each major disease category.

10. The method of claim 7, wherein the criteria assigning the overall clinical risk group comprise:

defining criteria for a series of risk groups ranked in order of declining severity;

comparing the primary chronic diseases to the criteria for each risk group, and assigning the most severe clinical risk group for which the criteria are met.

12. The method of claim 7, further comprising defining criteria for aggregating the clinical risk group and severity of illness rating to assign at least one aggregated clinical risk group and severity of illness rating to a group of patients.